510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax number of the Applicant

Guidant Corporation
Cardiac Surgery
3200 Lakeside Drive
Santa Clara, CA 95054

Telephone: (408) 845-1842
Fax: (408) 845-1855

B. Contact Person

Anne Schlagenhaft
Regulatory Affairs Associate

C. Date Prepared

September 9, 2002

D. Device Name

Trade Name: Guidant Essex Endoscope

Classification Name: Endoscope and accessories

E. Device Description

The Essex Endoscope consists of a shaft that houses glass fibers for light delivery and an optical lens system for image return. The distal shaft has a window for viewing. The proximal hub has a light guide post for attachment of light guides and an eyepiece with a clear viewing window for attachment of medical camera couplers. The Endoscope provides illumination and visualization of the working space during surgical procedures.

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F. Intended Use

The Essex Endoscope is indicated for use in general endoscopic procedures and other minimally invasive surgical procedures to visualize a surgical working cavity.

G. Substantial Equivalence

The Endoscope is substantially equivalent to the 5mm Endoscope, cleared under K960637 on June 14, 1996. The design of the Essex Endoscope is identical to the current Endoscope with a slightly smaller diameter, shorter shaft, and a right angle viewing port. The subject device is composed of materials that are identical to the currently marketed device. The Endoscope is substantially equivalent in intended use, materials, manufacturing processes, technological characteristics, and components to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2002

Guidant Corporation
c/o Ms. Michelle Weidman
Office Assistant Coordinator
KEMA Medical
4377 County Line Road
Chalfont, PA 18914

Re: K023627
Trade/Device Name: Essex Endoscope Model SXD-1000
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 25, 2002
Received: October 28, 2002

Dear Ms. Weidman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 023627

Device Name: Guidant Essex Endoscope

Indications For Use:

The Endoscope is indicated for use in general endoscopic procedures and other minimally invasive surgical procedures to visualize a surgical working cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023627